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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,685	04/17/1998	SAM D. SANDERSON	UNMC63102	8287

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/051,685	SANDERSON et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 4/5/02, 8/5/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1, 3-17, 25 is/are pending in the application.

Of the above claim(s) 25 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1, 3, 7, 10-14, 16-17 is/are rejected.

☑ Claim(s) 4-6, 8-9, 15 is/are objected to.

☑ Claim(s) 1, 3-17, 25 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

The claims pending and under examination are 1 and 3-17.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7 "said targeting moiety" lacks antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3. 10-11, 13 and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Romet-Lemonne et al. (U.S. 6,248,332) in light of Guyre et al.

Romet-Lemonne et al. teach immunogens which comprise a binding agent which binds a cell surface receptor of an antigen presenting cell (APC). Particularly preferred as a binding agent is an antibody which binds an Fc. Gamma. R I. This binding agent can be coupled or fused to a proteinaceous antigen. The binding agent of Romet-Lemonne et al. permits internalization of the antigen and enhances antigen presentation; this agent thus corresponds to applicant's "targeting ligand". Applicant should note particularly col. 1, lines 41-44; col. 2, lines 43-63; col. 3, line 55 - col. 4, line 55; col. 5, lines 5-10; col. 6, lines 23-25; and col. 6, line 58 - col. 7, line 5.

From the above, it is considered that claims 1, 3, 10-11, 13 and 17 are anticipated. While Romet-Lemonne et al., do not teach the instantly recited aspect that the binding agent ("targeting ligand") incurs signal transmission, this property would be reasonably considered as inherent to the conjugates/fusion proteins of Romet-Lemonne et al., since these are directed to the Fc. gamma. R.I. receptor, and since applicant has disclosed (pages 16-17) that this receptor is an example of contemplated target receptors on the APC and since applicant has contemplated (page 19) antibodies directed to APC - receptors as appropriate targeting ligands. Also, Guyre et al. Show that the particular antibodies taught by Romet-Lemonne trigger FcR function.

Regarding claim 16, note teachings of tumor associated/specific antigens by Lemonne et al. (e.g. col. 7, lines 33-39 and col. 8, lines 23-28).

If applicant traverses, he must show by comparative tests that the anti Fc. gamma. R I. conjugates of Lemonne et al. would not have all of the properties recited in instant claim 1.

Since the USPTO lacks laboratory facilities to conduct such comparative testing, the burden lies upon applicant to conduct the testing. Ex parte Gray 10 USPQ 2d 1922. Alternatively applicant could supply copies of literatively references which would indicate that it was art known that the binding agent used in the reference did not bind to the receptor in the fashion recited in claim 1.

Claims 1, 7, 10-11, 13 and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Laus et al. (U.S. 5,976,546) in light of Barclay et al.

Laus et al. disclose chemical immunogenic conjugates or recombinant fusion proteins of a dendritic cell binding protein (corresponding to the instant "targeting ligand") and a peptide or polypeptide antigen (including known tumor markers/tissue - specific tumor antigens). The dendritic cell binding protein moiety is exemplified as GM-CSF. When the GM-CSF binds to high affinity receptors there is rapid internalization (col. 7, lines 39-41). GM-CSF receptors mediate signal transduction (Barclay et al. at page 471). From the above it is clear that claims 1, 10-11, 13 and 16 are anticipated; applicant is particularly referred to col. 3, lines 21-50; col. 4, lines 9-18; col. 5, lie 13 - col. 6, line 59; col. 7, lines 7-47.

Regarding claim 7, note links discussed at col. 3, line 50 and col. 9, lines 7-11. Regarding claim 17, note teachings of administration of the conjugates/fusion proteins as a vaccine; this would inherently involve use of a "biologically compatible medium."

As for Romet-Lemonne et al., applicant should address this rejection by demonstration from comparative data or from known teachings in the literature that the composition of the reference does not have properties recited in claim 1.

Claims 1, 3, 10-11 and 16-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Sandlie et al. (WO 96/22377).

Sandlie et al. teach fusion proteins in which an antigenic peptide is inserted into a non-CDR loop of an immunoglobulin. They teach the inserted epitope can be from an infective agent or from mutant proteins of cancer cells (page 3, lines 18-36 and claims 8-9). The immunoglobulin component can be non antigen specific and thus taken up by APCs via binding of its Fc region to an Fc receptor. It is deemed binding to Fc. gamma. R I., as recited in instant claim 3, would have been inherent since, this is a high affinity receptor for IgG (instant specification pages 16-17). Thus the fusion proteins of Sandlie et al. would inherently have all properties recited in instant claim 1. Claims 1, 3, 10-11 and 16 are thus anticipated.

Alternatively, the antigenic peptide can be inserted into a non-antigen binding CDR of an antibody specific for an APC receptor such as CD11C (page 7, lines 6-25), in order to permit antigen entry into the APC via binding of the immunoglobulin V-region ("head first" entry). Absent evidence to the contrary it is considered that such "head first entry via the CD11c receptor is mediated in accord with the limits of instant claim 1. Claims 1, 10-11 and 16 are thus anticipated.

Regarding claim 17, Sandlie et al. teach therapeutic or prophylactic use (claim 11), which would inherently involve administration in a "biologically compatible medium."

Citation of the Sandlie et al's WO publication is deemed proper since applicant's provisional application does not provide benefit for the instantly rejected claims -- i.e. due to a species-genus relationship between the two, MPEP 201.11.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romet Lemonne et al. in view of Kennedy et al. (Clin Chim Acta 70, 1-31, 1976).

Romet-Lemonne et al. have be cited supra against claim 1. Romet-Lemonne et al. teach (col. 6, lines 58-65) that the binding agent (targeting ligand) and protein antigen can be biochemically coupled by known techniques.

Romet-Lemonne et al. thus point one to a reference such as that of Kennedy et al., which shows numerous art known reagents for coupling proteins. Numerous of these bifunctional coupling reagents contain alkyl chains or aromatic rings between the two reactive functional groups. Such chains or rings would inherently provide a "spacer moiety" when employed to couple the anti-Fc. gamma. R I. antibody of Romet-Lemonne et al. to a practienacious antigen.

Claims 1. 10 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romet-Lemonne et al. or Laus et al. in view of Sipe et al. (5,262,303).

The primary references have been cited supra for teaching conjugates or fusion proteins comprised of a targeting ligand and proteinaceous antigen, against which one desires to raise antibodies. Sipe et al. show that SAA is a known protein antigen that one would want to detect in immunoassay. It thus would have been obvious to obtain antibodies thereto by immunization with the conjugates or fusion proteins of Romet-Lemonne et al. or Sipe et al. containing SAA as the antigenic component.

Claims 1, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romet-Lemonne et al., Laus et al., or Sandlie et al. any in view of Finn et al. (5,827,666) or McKenzie et al. 5,989,552).

The primary references have been cited supra for showing the instant molecular "adjuvants" containing a tumor antigen or epitope thereof. Finn et al. Or McKennzie et al. each teach that Mucin-1 is a known tumor antigen, against which it is desirable to immunize patients. Thus it would have been obvious to provide Mucin-1 as the antigenic component of any of the molecular constructs of Romet-Lemonne et al., Laus et al. or Sandlie et al.

Claims 4-6, 8-9 and 15 contain subject matter allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

D. Saunders:jmr

October 18, 2002